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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,469	03/01/2004	Mark Deem	020979-001910US	2103

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EXAMINER	
EREZO, DARWIN P	
ART UNIT	PAPER NUMBER
3773	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/791,469	DEEM ET AL.	
	Examiner	Art Unit	
	Darwin P. Erezo	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,18-24 and 33-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16,18-24 and 33-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Upon further review of the applicant's specification and the Restriction Requirement mailed on 6/24/08, the Examiner is withdrawing the species election between the embodiment shown in Fig. 1, 3, 4, 5, 6 and 10 because the embodiments are disclosed to be obvious variants of each other.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 3/10/09 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 9-16, 18-24, 33-36 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,129,756 to Kugler et al. and in view of US 2003/0236567 to Elliot.

Kugler discloses a stent-graft device comprising at least one self-expandable member **10** (col. 10, ll. 48-49); at least one tubular graft member **40,41** coupled to the stent member, the tubular graft member having leg members **20,30** and coupled with a self-expandable iliac stent (shown in Fig. 2); wherein the leg members are fully capable

of being removed from the main graft members; wherein the self-expandable stent member **10** has a proximal portion that is not attached to the graft member and acts as an anchoring member at any location along vascular system, including a location superior to the renal arteries branching from the abdominal aorta or a location inferior to the renal arteries branching form the abdominal aorta; wherein the stent is formed from a wire (thus joining the unattached portion of the stent to the attached portion of the stent).

Kugler is silent with regards to the device comprising a skirt graft member coupled to the stent member and the graft member, wherein the skirt member is configured to contact the inner wall of an aortic aneurysm; and wherein the graft member has two sinusoidal members that are helically intertwined.

However, Elliot discloses a similar stent-graft device for treating aneurysm, wherein the device has a skirt **18** that is configured to contact the inner wall of an aneurysm. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kugler to have a skirt portion as disclosed by Elliot because the skirt provides a seal between the aneurysm and the device.

With regards to the leg members being helically intertwined, it is noted that the leg members of Kugler are disclosed as having corrugated portions **25,35** that provide enhanced longitudinal flexibility for the leg members, which perform the same functions as the applicant's helically intertwined leg members. Furthermore, the corrugated portions have sufficient flexibility and is fully capable of being intertwined together to

form a helical shape. Therefore, it would have been obvious to one of ordinary skill in the art to modify the shape of the corrugated portions to have a helical shape since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966). It would also only require the user to intertwined the already flexible corrugated portions of Kugler.

7. Claims 2-7 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. in view of Elliot, as applied to the claims above, and in further view of US 6,168,621 to Vrba.

The modified device of Kugler discloses all the limitations of the claims except for the stent member comprising both a self-expanding stent member and a balloon-expandable stent member. However, Vrba discloses a stent having both a self-expanding stent member and a balloon expandable stent member. This configuration is provided to allow immediate expansion of the stent member upon release, which will aid in placement of the stent during release but prior to using a balloon (col. 2, lines 4-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the stent member of Kugler to include both self-expanding and balloon-expandable stent members because it would allow the stent member to expand immediately upon release to position the stent in the right location prior to the expansion of a balloon, which would fully expand the entire stent member.

Vrba further discloses that the self-expanding stent members and the balloon-expanding stent members can be arranged in alternating sequence (col. 2, lines 50-55); wherein the stent member is made of nitinol (col. 2, line 7).

Vrba is silent with regards to the stent member being formed from stainless steel or to how the self-expanding stent members or the balloon-expanding stent members are connected to each other. However, the examiner takes Official notice that the use of stainless steel in medical devices, especially stents, are extremely well-known, and that connecting stent portions via welding, adhesive, soldering are also well-known in the art (as evidenced by US 5,843,176; col. 3, lines 49-57). Therefore, such modifications would be obvious to one of ordinary skill in the art. It is further noted that the common knowledge or well-known in the art statement is taken to be admitted prior art because the applicant failed to traverse the examiner's assertion of official notice.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kugler et al. in view of Elliot and Vrba, as applied to the rejections above, and in further view of US 6,945,994 to Austin et al.

The modified device of Kugler discloses all the limitation of the claim except for the stent member having diamond-shaped members. However, Austin discloses a similar type of stent as Vrba, wherein the stent has both self-expanding and balloon-expandable stent members, and wherein the stent can have diamond-shaped, rectangular or even square patterns (col. 5, line 62). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Kugler to include diamond-shaped stent members because Austin discloses that it is well known in the art for stents to have various shapes, including diamond-shapes.

Response to Arguments

9. Applicant's arguments with respect to claims 1-16, 18-24, 33-40 in the reply filed on 3/7/08 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezo/
Primary Examiner, Art Unit 3773